

K022537

510(k) Summary

SEP 13 2002

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Date of Summary Preparation: February 25, 2001

Manufactures Contact Person:

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 Colin Medical Instruments Corp.
 5850 Farinon Drive
 San Antonio, TX. 78249

Trade Name: Press-Mate PM-2100 Vital Signs Monitor**Classification Name, Classification Number, Class, Classification Reference:**

Classification Name	Class Number	Class	21CFR§
Pulse rate monitor	74BWS	II	870.2300
Blood pressure computer	DSK	II	870.1110
Non-indwelling blood pressure monitor	74DXN	II	870.1130
Blood pressure alarm		II	870.1100
Clinical electronic thermometer	80BWX	II	880.2910
Pulse Oximeter	74 DQA	II	870.2700
Finger Oximeter		II	
Paper chart Recorder		II	870.2810

Special Controls: There are no regulatory standards or special controls applicable for this device, however, the device voluntarily adheres to the U.S. FDA Guidance Document "NON-INVASIVE BLOOD PRESSURE (NIBP) MONITOR, Version 1.0, dtd. March, 1997 and ANSI/AAMI SP10-1992.

Indications for Use: The Press-Mate PM-2100 patient monitor is intended to monitor a single patient's vital signs in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device capable of monitoring:

Pulse rate (via oximetry data)
 Non-invasive pressure (systolic, diastolic and mean oscillometric NIBP)
 Temperature
 Blood oxygen saturation (Sp02 via finger oximeter)

This device is intended for use by qualified healthcare personnel trained in its use.

Device Description: The Press-Mate PM-2100 Series Monitor is a fully portable multiparameter monitoring device which provides the capability for noninvasive monitoring of adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings. It is a prescription device intended for use only by health care professionals. The oscillometric method, upper arm measurement is employed. The PM-2100 includes, temperature via ALARIS® electronic predictive thermometry and Nellcor® oxygen saturation (Pulse Oximetry) utilizing the finger for the placement of the sensor. The monitor uses a single tube reusable cuff or may be optionally used with a disposable single tube cuff.

The PM-2100 has an optional replaceable and rechargeable battery as well as an optional thermal printer to print displayed data, waveforms and trend information. A liquid crystal display (LCD) and (LED) provides high visibility and clarity in most light conditions. The available parameters displayed will depend on the mode selected by the user.

Visual and audible alarms are provided to alert the user to monitor operational conditions or should patient values exceed default or operator-set high/low limits.

Model 2100: Non – Invasive Blood Pressure and Pulse Rate

Model 2110: Non – Invasive Blood Pressure and Pulse Rate; and Nellcor® Pulse Oximetry and Pulse Rate

Model 2120: Non – Invasive Blood Pressure and Pulse Rate; and Monitor/Predictive Oral/Rectal Temperature

Model 2140: Non - Invasive Blood Pressure and Pulse Rate; and Monitor/Predictive Oral/Rectal Temperature and Nellcor® Pulse Oximetry and Pulse Rate

This portable device includes an optional integrated printer and is capable of operation from an external AC power source or an internal rechargeable battery. The device uses the same technology and materials as the predicate devices, the Press – Mate 8800 (K890876 cleared 6/22/89) and the Press – Mate Advantage (K 973637 cleared 9/25/98)

The following accessories are available for use with the device:

1. Power cord
2. Printer Paper
3. Operations Manual
4. Disposable cuffs
5. Reusable cuffs
6. Cuff extension hose
7. Temperature probe
8. Finger Probe
9. Extension Cable

Substantially Equivalent Commercially Available Devices: The Press-Mate PM-2100 Monitor is substantially equivalent to the following commercially available predicated devices with respect to indications for use, device design, materials, and method of manufacture.

Colin Corporation, Press-Mate 8800 Monitor (K890876; K921048C; K942871)
Colin Corporation, Press-Mate Advantage Monitor (K973637)

Substantial Equivalence Comparison: The Press-Mate PM-2100 is similar to commercially available devices with respect to intended use, material, design and operation principles as follows:

1. Operational Principles: the basic operational principles of the Press-Mate PM-2100 monitor and the predicate devices are to provide an indication of a patient's vital signs and provide an indication, usually via an alarm, when parameters fall outside of preset limits. The parameters that are measured and displayed are the same as those for the predicate devices.
2. Indications and Contraindications: Relative indications and contraindications for the Press-Mate PM-2100 monitor and commercially available devices for similar intended uses are the same.

Assessment of non-clinical performance data for equivalence: Currently there are no FDA standards for this device. However, the Press-Mate PM-2100 complies with:

U.S. FDA Guidance Document "NON-INVASIVE BLOOD PRESSURE (NIBP) MONITOR, Version 1.0, dtd. March, 1997

ANSI/AAMI SP10-1992

CSA Standard C22.2, No. 125-1984, Eletromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

Clinical and Bench Testing

Non - Invasive Blood Pressure (NIBP)

For NIBP performance, Colin used ANSI/AAMI SP10-1992: "Electronic or automated sphygmomanometers" and ANSI/AAMI SP10A-1996: Amendment to ANSI/AAMI SP10-1992: American National Standard for Electronic or Automated Sphygmomanometers.

The following requirements of ANSI/AAMI SP10 and SP10A were met:

- Labeling (4.1)
- Stability (4.2.4, environmental requirements, 4.2.1, 2.2.2, and 4.2.3)
- Safety (4.3)
- Performance (4.4)

To evaluate environmental performance, Colin met the requirements contained in the November 1993 Draft Reviewer Guidance for Pre-market Notification Submissions of the Anesthesiology and Respiratory Devices Branch of the Division of Cardiovascular, Respiratory, and Neurological Devices.

Clinical Study for Accuracy-Overall System Efficacy:

Accuracy of the NIBP algorithm was established in the adult, pediatric, and neonatal populations with the ANSI/AAMI SP10 clinical study for the Press – Mate 8800 and the Press – Mate Advantage monitors

The NIBP parameter of the new monitor has the same NIBP algorithm that calculates blood pressure from measured oscillations as the Press – Mate 8800 (K890876); and the Press – Mate Advantage (K973637). Also, an accuracy study was performed on the new monitor according to AAMI SP – 10 in which 85 adult and pediatric subjects were tested.

Moreover, the NIBP parameter of the new monitor has the same intended use and labeling claims as the Press – Mate 8800 and the Press – Mate Advantage; the same software runs in the same processor family under the same operating system with the same programmer as the predicate device; and the same accessories-air hoses and blood pressure cuffs.

Bench Testing, ANSI/AAMI SP10

With the exception of the environmental performance, the new device was subject to the remainder of ANSI/AAMI SP10 bench testing requirements, including:

- Stability: 4.2.4.1 Voltage Range; and 4.2.4.2 Life
- Safety Requirements: 4.3.1.1 Maximum Cuff Pressure; 4.3.2 Cuff Deflation; 4.3.2 Electrical Safety; and 4.3.3 Conductive Components
- Performance Requirements: 4.4.1 Pressure Indicator Accuracy; and 4.4.3 Battery-Powered Devices.

The new device passed all tests.

Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act and 12 CFR Part 807, and based on the information provided in this premarket notification, Colin Medical Instruments concludes that the new device, the Press-Mate PM-2100 monitor is safe, effective and substantially equivalent to the predicate device as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Colin Medical Instruments Corporation
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K022537

Trade Name: Press-Mate PM-2100 Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 29, 2002
Received: August 30, 2002

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

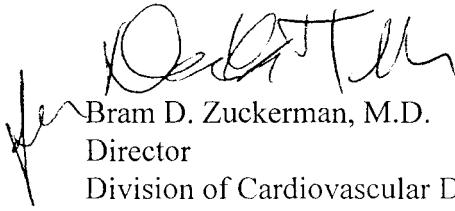
Page 2 – Mr. Robert Mosenkis

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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Device Name: Vital Sign Monitor, Patient Monitor; including the following parameters

Pulse Oximetry (SPO₂)

Non-invasive Systolic & Diastolic Blood Pressure Measurement (NIBP)
Temperature Measurement

Indications for Use:

The Press-Mate PM-2100 patient monitor is intended to monitor a single patient's vital signs in the hospital, outpatient surgery practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device is capable of monitoring"

Pulse rate (via oximetry data)

Non-invasive pressure (systolic, diastolic and mean oscillometric NIBP)

Temperature

Blood oxygen saturation (SPO₂ via finger oximeter)

This device is intended for use by qualified healthcare personnel trained in its use.

The device labeling will indicate:

CAUTION: Federal Law (USA) Prohibits Dispensing Without Prescription

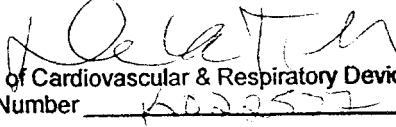
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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use X
(Per 21 CFR 801.109)

Over-The-Counter Use _____


Division of Cardiovascular & Respiratory Devices
510(k) Number 502573

(Optional Format 1-2-96)